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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/365,065 07/30/99 COLLINS D 10847/002001

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EXAMINER

ZEMAN, R

ART UNIT

PAPER NUMBER

1645

4

DATE MAILED:

01/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/365,065

Applicant(s)

Collins

Examiner
Robert A. Zeman

Group Art Unit
1645



☒ Responsive to communication(s) filed on Jul 30, 1999.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-21 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-21 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-21 are pending and under examination. The term "substantially all" which is recited in claims 2 and 20 will be interpreted to mean **at least 80%** as disclosed on page 10, paragraph 3 of the specification.

Specification

The use of the trademarks Texas Red™, Oregon Green™, Cascade™, Nonidet P40 and Triton-X 100 have been noted in this application. Each should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claims 1-19 are drawn to methods for detecting binding pairs. Claims 20 and 21 are drawn to kits for detecting binding pairs.

Claim Rejections - 35 USC § 102

Claims 20 and 21 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chandler et al (U.S. Patent 5,981,180).

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Chandler et al. disclose a composition comprising a solid phase reagent and labeled antibodies with specific binding affinities for differing binding partners that can be measured using flow cytometry. Additionally, it would be obvious to use a label or package insert to list the contents of said composition. The composition of Chandler is believed to anticipate the subject matter of claims 20 and 21 since the components are the same, but if not, it would have been obvious to package the components in the form of a kit for reasons of convenience and economy.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kortright et al. (U.S. Patent 4,870,003) in view of Jackson et al. (U.S. Patent 5,776,709).

Applicant claims methods and kits for simultaneously detecting both members of a binding pair utilizing fluorescent labels. The methods consists of coating a solid phase reagent with "capture" antibodies specific for one member of the binding pair; contacting said particles with test sample to bind first member of the binding pair (if present); adding fluorescently

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labeled antibodies specific first member of the binding pair and fluorescently labeled antibodies specific for the remaining member of the binding pair; and measuring labels using flow cytometry.

Kortright et al. disclose a solid-phase immunoassay for the simultaneous detection of both members of a binding pair in physiological fluid through the utilization of labeled antibodies with specific binding affinities said binding pair members. Kortright et al. further disclose methods consisting of coating a solid phase reagent with a capture antibody (anti-HIV monoclonal antibody); exposing said solid phase reagent to a biological sample to bind one member of the binding pair; and adding labeled antibodies to detect the levels of each member of the binding pair (see column 4, lines 1-32). Kortright et al, however, disclose the use of enzyme labels for measuring binding pair levels and the level of the second binding pair member is determined indirectly as an increase over the "spiked" positive control. Jackson et al. disclose not only the use of fluorescently labeled antibodies but also the methods for using multiple stains simultaneously in flow cytometry (see example 1 in columns 12 and 13 for an example) which allows for the direct measurement of the level of each binding pair member. Jackson et al also disclose the benefit of using multiple fluorescent labels as opposed to other labeling techniques (such as enzyme labels). Multiple fluorescent labels "provide(s) a means for obtaining a maximum amount of information with the minimal sample manipulation, resulting in time savings both in sample preparation and instrument data acquisition" The method allows detection of two or more subpopulations depending on the number of fluorochrome-labels used.

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Therefore, it would have been obvious to one of skill in the art to use the fluorochrome labeling disclosed by Jackson et al. in the methods disclosed by Kortright et al. in order to reap the benefits of direct measurement of each label (and hence the each binding pair member) as well as the reduction in sample preparation and data acquisition. One would have a reasonable expectation of success since Kortright et al. suggest the use of other labeling systems, specifically "fluorescers" (see column 7 lines 29-32). Additionally, the methods disclosed by Kortright et al. can be applied to a myriad of binding pairs including: various viruses and antibodies; enzymes and its ligands or substrates; cytokines and their receptors; and vitamins and their receptors to name a few.

Conclusion

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Anthony Caputa, can be reached at (703)308-3995.


DONNA WORTMAN
PRIMARY EXAMINER 1/3/02